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| Comp. Ex. 69 | 2.8 | 3.6 | 3.6 | 3.0 | 1.8 |
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CLAIMS

- 5 1. A powdery composition for nasal administration characterized in that
(1) the composition contains (i) a drug, (ii) a water-absorbing and gel-forming base material of one kind or more selected from the group comprising hydroxypropyl cellulose, hydroxypropylmethyl cellulose,
10 methyl cellulose, hydroxyethyl cellulose and sodium carboxymethyl cellulose and (iii) a water-absorbing and water-insoluble base material of one kind or more selected from the group comprising crystalline cellulose, α -cellulose, cross-linked sodium carboxy-methyl cellulose, cross-linked starch, gelatin, casein, tragacanth gum, polyvinyl
15 pyrrolidone, chitin and chitosan.
(2) the content of the water-soluble and gel-forming base material is about 5-40 wt % based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material, and
20 (3) the drug is unevenly dispersed more on/in the water-absorbing and water-insoluble base material than on/in the water-absorbing and gel-forming base material.
2. A powdery composition for nasal administration described in Claim 1, wherein (i) average particle diameters of the water-absorbing and gel-forming base material and the water-absorbing and water-insoluble base material in at least 90 wt % based on the particles are in the range of 10-350 μ m, and (ii) the state in which the drug is unevenly dispersed more on/in the water-absorbing and water-insoluble base material than on/in the water-absorbing and gel-forming base material is a state in which the drug is adhered according to their compounding ratio.
3. A powdery composition for nasal administration described in Claim 1 or Claim 2, wherein the drug exists in a state in which the drug is adhered to the water-absorbing and water-insoluble base material in
35 60 wt % or more based on the drug.
4. / A powdery composition for nasal administration described in Claim 1, wherein the state in which the drug is dispersed more on/in the water-absorbing and water-insoluble base material than on/in the water-absorbing and gel-forming base material is obtained by making the average particle diameter of the water-absorbing and water-insoluble base material larger than that of the water-absorbing and gel-forming base material.
- 40 5. / A powdery composition for nasal administration described in Claim 4, wherein the water-absorbing and water-insoluble base material has an average particle diameter of 10-350 μ m in at least 90 wt % based
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on the particles, and the water-absorbing and gel-forming base material has an average particle diameter of 10-105 μ m in at least 90 wt % based on the particles.

6. A powdery composition for nasal administration described in Claim 4, wherein the water-absorbing and water-insoluble base material has an average particle diameter of 10-250 μ m in at least 90 wt % based on the particles, and the water-absorbing and gel-forming base material has an average particle diameter of 10-65 μ m in at least 90 wt % based on the particles.

7. A powdery composition for nasal administration described in any one claim among Claim 1 to Claim 6, wherein the drug is selected from the group comprising non-peptide/non-proteinaceous drugs and peptide/proteinaceous drugs having molecular weights of 30,000 or less.

8. A powdery composition for nasal administration described in Claim 7, wherein the non-peptide/non-proteinaceous drug is one kind or more selected from the group comprising anti-inflammatory steroids or nonsteroidal anti-inflammatory drugs, analgesic anti-inflammatory agents, antitussive expectorants, antihistaminic agents, antiallergic drugs, antiemetic drugs, hypnotics, vitamin preparations, sex steroid hormones, antineoplastic drugs, antiarrhythmic drugs, antihypertensive drugs, antianxiety drugs, psychotropic drugs, antiulcer drugs, cardiotonics, analgesics, bronchodilators, treating agents for obesity, antithrombotic drugs, antidiabetic drugs, muscle relaxants and anti-rheumatics.

9. A powdery composition for nasal administration described in Claim 7, wherein the peptide/proteinaceous drug is one kind or more selected from the group comprising luteinizing hormone-releasing hormones, growth hormone-releasing factors, somatostatin derivatives, vasopressins, oxytocins, hirudin derivatives, enkephalins, adrenocorticotrophic hormone derivatives, bradykinin derivatives, calcitonins, insulins, glucagon derivatives, growth hormones, growth hormone-releasing hormones, luteinizing hormones, insulin-like growth factors, calcitonin gene-related peptides, atrial natriuretic polypeptide derivatives, interferons, erythropoietin, granulocyte colony forming-stimulating factor, macrophage forming-stimulating factor, parathyroid hormones, parathyroid hormone-releasing hormone, prolactin, thyroid-stimulating hormone-releasing hormone and angiotensins.

10. A powdery composition for nasal administration described in any one claim among Claim 1 to Claim 6, wherein the drug is a peptide/proteinaceous drug having a molecular weight of 500-1500, and the amount of the water-absorbing and gel-forming base material is about 5-30 wt % based on the total of the water-absorbing and water-insoluble base material and the water-absorbing and gel-forming base material.

11. A powdery composition for nasal administration described in Claim 10, wherein the peptide/proteinaceous drug is one kind or more

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selected from the group comprising vasopressins, luteinizing hormone-releasing hormones, growth hormone-releasing factors, somatostatin derivatives, oxytocins, hirudin derivatives, enkephalins, adrenocorticotrophic hormone derivatives and bradykinin derivatives.

5 12. A powdery composition for nasal administration described in any one claim among Claim 1 to Claim 6, wherein the drug is a peptide/proteinaceous drug having a molecular weight of 1500-30,000 and the amount of the water-absorbing and gel-forming base material is about 5-20 wt % based on the total of the water-absorbing and water-
10 insoluble base material and the water-absorbing and gel-forming base material.

13. A powdery composition for nasal administration described in Claim 12, wherein the peptide/proteinaceous drug is one kind or more selected from the group comprising calcitonins, insulins, glucagon
15 derivatives, growth hormones, growth hormone-releasing hormones, luteinizing hormones, insulin-like growth factors, calcitonin gene-related peptides, atrial natriuretic polypeptide derivatives, interferons, erythropoietin, granulocyte colony-stimulating factor, macrophage-stimulating factor, parathyroid hormones, parathyroid hormone-releasing hormone, prolactin, thyroid-stimulating hormone-releasing
20 hormone and angiotensins.

14. A powdery composition for nasal administration described in any one claim among Claim 1 to Claim 13, wherein the water-absorbing and water-insoluble base material is one kind or more selected from the
25 group comprising crystalline cellulose, α -cellulose, cross-linked sodium carboxymethyl cellulose, cross-linked starch, gelatin, casein, tragacanth gum, polyvinyl pyrrolidone, chitin and chitosan.

15. A powdery composition for nasal administration described in any one claim among Claim 1 to Claim 13, wherein the water-absorbing and
30 water-insoluble base material is crystalline cellulose.

16. A powdery composition for nasal administration described in any one claim among Claim 1 to Claim 13, wherein the water-absorbing and gel-forming base material is one kind or more selected from the group comprising hydroxypropyl cellulose, hydroxypropylmethyl cellulose,
35 methyl cellulose and sodium carboxymethyl cellulose.

17. A powdery composition for nasal administration described in any one claim among Claim 1 to Claim 13, wherein the water-absorbing and gel-forming base material is hydroxypropyl cellulose.

18. A powdery composition for nasal administration described in
40 Claim 17, wherein the hydroxypropyl cellulose has a viscosity of 150-4000 cps in 2% aqueous solution.

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